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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,104	12/17/2001	Sung-Yun Kwon	OPF 38.01	2437

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Thomas P. McCracken
POWDERJECT TCHNOLOGIES INC.
6511 Dumbarton Circle
Fremont, CA 94555

EXAMINER	
ALEXANDER, LYLE	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/023,104	KWON, SUNG-YUN
	Examiner	Art Unit
	Lyle A Alexander	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,10-11, 13, 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chick et al.(USP 5,342,789).

Chick et al. teach a method and apparatus for in vivo or vitro blood glucose determination. Column 2 teaches use of specific binding pairs comprising a labeled ligand and a labeled glycoconjugate each with a different fluorophore. The glucose analyte and the glycoconjugate competitively bind to the ligand. The claimed reporter system has been read on the taught labels. The quantification of the fluorophores is accomplished by nonradiative fluorescence resonance energy transfer (FRET). Column 3 teaches the reactants can be placed in, on or under the skin and can

measure glucose concentrations in the range of 0.5-18 mg/ml. Column 6 lines 35+ teach a suitable ligand with high specificity for glucose is concanavalin A. Column 9 lines 10+ teach the reactants can be encapsulated in spheres and contained in a transcutaneous patch which has been read on the claimed "occlusive backing". The claimed "drape characteristics" has been read in light of page 4 of the specification that teaches this as the ability to drape over the body and has been read on the taught patch that is also attached or draped over the body.

Claims 1-20,22-25 and 27-34 rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cote et al. (USP 6,485,703).

Cote et al. teach compositions and method for in vivo glucose detection. Column 11 lines 15+ teach FITC-dextrans and TRITC-ConA as the specific binding pair(SBP) for the competitive binding of glucose and suitable polymer matrix to support the (SBP). Column 12 teaches use of a "smart tattoo" to place FITC-dextrans and TRITC-ConA immobilized in a polymer matrix 0.05mm below the skin that has been read on the claimed particle penetration of 50 microns. Also claim 4 is specific to a particle penetration of 50 microns. Claim 6 teaches the particle diameter of up to 10 microns which is within the claimed range. Column 15 characterizes fig. 2 as showing the competitive binding effect FITC-dextrans and TRITC-ConA to detect glucose by measurements of 520 nm emissions. The "smart tattoo" has been read on the claimed disruption the skin surface and accelerating the particles into the skin. The polymer matrix has been read on the taught "occlusive backing". Claim 2 does not specify the where occlusive backing is draped (e.g. on the surface or in the skin) and has been

properly read on the taught polymer matrix. Page 6 of the application describes the "needle less syringe" as a device for injecting the particles in the skin. In light of the definition taught by the specification, the claimed "needle less syringe" has been read on the taught "smart tattoo" that accomplishes the same function of injecting the particles in the skin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote et al.

Cote et al. is silent to the acceleration at which the particles are deposited in the skin.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one

that has predictable and well-known results. Selection of the velocity of a particle would have the well-known and expected result of controlling the penetration made by the particle. It would have been within the skill of the art to modify Cote et al. and select a velocity, such as 100 to 2,500 m/sec. , sufficient to deposit the polymer matrix at a depth of 50 microns below the surface of the skin as optimization of a result variable.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. March et al. teaches a FITC-dextrans and TRITC-ConA competitive binding assay for detecting glucose level in ocular fluids.

Loeb et al. teach s subcutaneous glucose biosensor utilizing FITC-dextrans , TRITC-ConA and FRET analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Lyle A Alexander
Primary Examiner
Art Unit 1743